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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,695	08/26/1999	DAVID M. NEVILLE	14014.0225	6915

36339 7590 09/29/2003

NATIONAL INSTITUTE OF HEALTH
C/O NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30303

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/29/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/383,695

Applicant(s)
Neville et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 22, and 26-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-29 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9, 10, and 22 is/are rejected.
- 7) ☒ Claim(s) 5, 7, and 8 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Interview Summary

Application No.

09/383,695

Applicant(s)

Neville et al

Examiner

Ungar

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All participants (applicant, applicant's representative, PTO personnel):

(1) Ungar(3) A. Caputa(2) T. McKeon(4) G. LanierDate of Interview Apr 3, 2003

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:Claim(s) discussed: All pending

Identification of prior art discussed:

NoneAgreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicant's arguments drawn to priority to provisional application 60/015,459 were found convincing and the priority of the claimed invention is hereby set to April 15, 1996. Thus, the primary reference of the rejection under 35 USC 103 is now a 102(a) reference. Applicant will submit a declaration that the reference is his own work in order to overcome the rejection. Further, upon review of the specification, the art of record and the prosecution history, it is found that the claims to inducing immune tolerance are enabled and the rejection under 112, first paragraph drawn to immune tolerance is hereby withdrawn.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

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1. The Amendment and Declaration filed April 11, 2003 (Paper No. 29) in response to the Office Action of October 21, 2002 (Paper No. 27) and the Telephone Interview of April 3, 2003 (Paper No. 28) are acknowledged and have been entered. Claims 1-10, 22, 26-29 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are maintained:

Double Patenting

4. Claims 1-4, 6, 9-10 and 22 remain rejected under nonstatutory double patenting and claims 5 and 7-8 are rejected under nonstatutory double patenting for the reasons previously set forth in Paper No. 13, Section 8, pages 5-8, Paper No. 20, Section 8, pages 5-6, Paper No. 27, Section 5, page 5.

Applicant argues that since the priority date claimed for both the instant application is April 15, 1996, the double patenting rejection is moot.

The argument has been considered but has not been found persuasive because MPEP 804.02 specifically states in-part that:

Public Law 103-465 (1994) amended 35 U.S.C. 154(a)(2) to provide that any patent issuing on a utility or plant application filed on or after June 8, 1995 will expire 20 years from its filing date, or, if the application claims the benefit of an earlier filed application under 35 U.S.C. 120, 121, or 365(c), 20 years from the earliest filing date for which a benefit under 35 U.S.C. 120, 121, or 365(c) is claimed. Therefore, any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c), subject to the provisions of 35 U.S.C. 154(b).

Since 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process, 35 U.S.C. 154 does not

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ensure that any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will necessarily expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). In addition, 37 CFR 1.321(c)(3) requires that a terminal disclaimer filed to obviate a judicially created double patenting rejection include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection. This requirement serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention (37 CFR 1.601(n)). See, e.g., *In re Van Ornum*, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Not insisting upon a terminal disclaimer to overcome a judicially created double patenting rejection in an application subject to a 20-year term under 35 U.S.C. 154(a)(2) would result in the potential for the problem that 37 CFR 1.321(c)(3) was promulgated to avoid.

Accordingly, a terminal disclaimer under 37 CFR 1.321 is required in an application to overcome a judicially created double patenting rejection, even if the application was filed on or after June 8, 1995 and claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the filing date of the patent or application which forms the basis for the rejection.

The instant application was filed on August 26, 1999, therefore a terminal disclaimer under 37 CFR 1.321 is required to overcome the standing double patenting rejection.

5. All other objections and rejections recited in Paper No. 27 are withdrawn.
6. Claims 26-29 are allowable.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

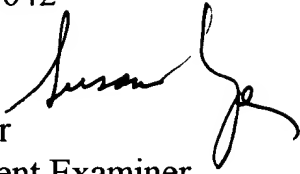
Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

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Susan Ungar
Primary Patent Examiner
September 24, 2003

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.